DETAILED ACTION

Response to Amendment

Amendment filed in 07/06/10 have been entered.

Claims 34-38 are present for examination.

Claims 1-33 are cancelled.

Specification

The amendment filed 07/06/10 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the new limitation "…a plurality of potential sites" does not disclose anywhere in the Specification.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 34 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. No where in the Specification discloses a limitation "a plurality of potential sites" as required in claim 34. Which are elements considered as potential sites?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sisley et al. (US 4,405,313) in view of Bierman (US 6,661,523) or Cianci (US 4,149,539).

Regarding claim 34, Sisley discloses a multiple catheter assembly, comprising:

a first catheter 12 having a first distal end region and a first proximal end region joined by a first intermediate section;

a second catheter 14 having a second distal end region and a second proximal end region joined by a second intermediate section;

first and second extension tube assemblies 24 and 26 having first and second distal end portions respectively associated with the first and second proximal end regions of the first and second catheters; and

a hub member is attachable to and around the first and second proximal end regions of the first and second catheters distally of the proximal ends thereof, after catheter implantation and subcutaneous tunneling and at a site along the first and second proximal end region selectable by the practitioner, such that portions of the proximal end regions of the first and second catheters extend through the hub member 22 and proximally beyond the proximal end of the hub member, to be connected to respective one of the first and second extension tube assemblies. See Figs. 1 & 4.

Sisley shows the hub member/splitter 22 but the hub member/splitter 22 is not initially separate hub member, as required in claim 34. The hub member/splitter 22 is attached but not releasably, however, the hub member/splitter 22 can be replaced with other releasably attachable hub member as below.

Bierman discloses in Figs. 6a-b that a catheter assembly comprising: a catheter; an initially separate hub assembly 20 adapted to be releasably attachable by a practitioner directly to and around the proximal end region of the catheter.

Alternatively, Cianci discloses a catheter assembly comprising: a catheter; an initially separate hub assembly 18 adapted to be releasably attachable by a practitioner directly to and around the proximal end region of the catheter, Figs. 8-10.

It would have been obvious to one having ordinary skill in the art at the time of invention by the applicant to modify the device of Sisley with a hub assembly, as taught by Bierman or Cianci, for the benefit of easy attachable or detachable for intended use purpose of the user.

It has been held that the recitation that the hub member is "capable of or adapted to be releasably attachable by a practitioner…" and the limitation "after catheter implantation and subcutaneous tunneling" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138. In this case, the limitation "after catheter implantation and subcutaneous tunneling..." is a step of performing in the device claim. It is considered as functional limitation. The combination of device Sisley in view of Bierman or Cianci will bring the result such as the hub member adapted to be releasably attachable by practitioner directly to and around the catheter.

Regarding claim 35, wherein the cross section shapes of the first and second proximal end region is circular; and the cross section shapes of the first and second distal end portions of the first and second extension tube is circular, see Figs. 1-3.

Claims 34-35 are alternatively rejected under 35 U.S.C. 103(a) as being unpatentable over Hobbs et al. (US 7,347,852) in view of Bierman (US 6,361,523).

Regarding claim 34, Hobbs discloses a multiple catheter assembly, comprising:

a first catheter 10/20 having a first distal end region and a first proximal end region joined by a first intermediate section;

a second catheter 12/22 having a second distal end region and a second proximal end region joined by a second intermediate section;

first and second extension tube assemblies having first and second distal end portions respectively associated with the first and second proximal end regions of the first and second catheters, Figs. 2-3.

Hobbs does not show a hub member as required in claim 34.

Bierman discloses in Figs. 6a-b that a catheter assembly comprising: a catheter; an initially separate hub assembly 20 adapted to be releasably attachable by a practitioner directly to and around the proximal end region of the catheter.

It would have been obvious to one having ordinary skill in the art at the time of invention by the applicant to modify the device of Hobbs with a hub assembly, as taught by Bierman, in order to support the catheter device and easy attachable or detachable for intended use purpose of the user.

It has been held that the recitation that the hub member is "capable of or adapted to be releasably attachable by a practitioner…" and the limitation "after catheter implantation and subcutaneous tunneling" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138. In this case, the limitation "after catheter implantation and subcutaneous tunneling..." is a step of performing in the device claim. It is considered as functional limitation. The combination of device Hobbs in view of Bierman or Cianci will bring the result such as the hub member adapted to be releasably attachable by practitioner directly to and around the catheter. The hub member of Bierman is located around V-shape portion of Hobbs, therefore, portions of the proximal end regions of the first and second catheters of Hobbs extend through the hub member of Bierman and proximally beyond the proximal end of the hub member through respective exits, to be connected to respective ones of the first and second extension tube assemblies.

Regarding claim 35, wherein the cross section shapes of the first and second proximal end region is circular; and the cross section shapes of the first and second distal end portions of the first and second extension tube is circular, see Fig. 4A.

Claims 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sisley et al. in view of Bierman/Cianci and further in view of Ash (US 5,947,953).

Alternatively, claims 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hobbs in view of Bierman and further in view of Ash (US 5,947,953).

Sisley in view of Bierman/Sisley discloses all claimed subject matter except for that the cross sectional shapes of the first and second intermediate sections of the first and second catheters is circular but not a semicircular, as requires in claim 36.

Alternatively, Hobbs in view of Bierman discloses all claimed subject matter except for that the cross sectional shapes of the first and second intermediate sections of the first and second catheters is circular but not a semicircular, as requires in claim 36.

Ash discloses a similar catheter device comprising: the cross sectional shapes of the first and second intermediate sections of the first and second catheters is semicircular, see Fig. 4F; and the first and second catheters have transition sections between the circular cross-sectional shapes of the first and second proximal end and distal end regions and the semicircular cross-sectional shapes of the first and second intermediate sections, see Figs. 1-4G.

It would have been obvious to one having ordinary skill in the art at the time of invention by the applicant to modify the device of Sisley or Hobbs with the semicircular cross sectional shapes of the first and second intermediate sections of the first and second catheter, as taught by Ash, in order to improve the blood flow rate in the catheter system.

Additionally, Applicant states that the beside the semicircular cross section shapes of catheter, other configurations may be used without departing from the spirit of the invention, such as, for example, oval, circular, elliptical, square...., see para [0032] of Specification. Therefore, one skill in the art would recognize that the circular cross section shape in Sisley can be modified in any shapes such as semicircular… is design choice.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sisley in view of Bierman and Ash and further in view of Cazal (US 5,800,414).

Alternatively, claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sisley in view of Hobbs in view of Bierman and Ash and further in view of Cazal (US 5,800,414).

Sisley in view of Bierman/Cianci and Ash discloses the invention substantially as claimed. Sisley discloses that the 2 catheters 12 and 14 are attached by 18a, see Fig. 3. However, the combination of Sisley in view Bierman and Ash does not clearly mention that the catheters 12 and 14 are attached by adhesive.

Alternatively, Hobbs in view of Bierman and Ash discloses the invention substantially as claimed. Hobbs in view of Bierman and Ash discloses the first and second catheter are splittably joined to each other by wire 46 not adhesive as requires in claim 38.

Cazal discloses a similar device, in which the first and second catheters are splittably joined to each other by adhesive 14 or 20. It is noted that the adhesive 14 or 20 is capable of being splitted if using sufficient force to tear it.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Sisley in view of Bierman/Cianci and Ash or Hobbs in view of Bierman and Ash, with an adhesive, as taught by Cazal, if one wished to easily join the two catheters.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 34-38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-37 of copending Application No. 10/974,267.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they device of instant claims are fully disclosed and covered by the claims in the copending application claims.

As noted that, claims 1-37 does not include the hub or an initially separate hub. However, the Applicant admitted that the hub 150 may be omitted is common sense or well-known in the art (see para 0036 of Specification or para 0050 of Application 10/974267). Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to the releasable hub, since it has been held that omission of an element and its function in a combination where the remaining elements perform the same functions as before involves only routine skill in the art.

This is the provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments with respect to claims 34-38 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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